BARBARA ANN

KARMANOS

CANCER INSTITUTE

Wayne State University

Testimony before the Senate Committee on Insurance
Support of Senate Bills 540 and 541
November 8, 2011

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Thank you Chairman Hune and members of the Committee for the opportunity to submit testimony today in support of Senate bills 540 and 541 – legislation that addresses one of the most important advances in cancer care in decades. Thank you to Senator Kahn for sponsoring this legislation.

This testimony is on behalf of the Barbara Ann Karmanos Cancer Institute - one of only 40 National Cancer Institute designated Comprehensive Cancer Centers in the country and was prepared by Dr. Charles Schiffer, multidisciplinary team leader for malignant hematology and Dr. Jeffery Zonder, a member of the multidisciplinary team for malignant hematology; with a clinical research focus on the application of new drugs for blood disorders like multiple myeloma (MM). Patient obligations made it impossible for them to be here today in person.

Throughout the years that Drs. Schiffer and Zonder have been practicing oncologists, they have seen many changes in the way we treat cancer. One example is that of Chronic Myeloid Leukemia (CML). According to the NCIs Surveillance Epidemiology and End Results (SEER) data from 1988 – 2001 the 5-year relative survival rate for CML was only 37.7 percent. But in 2001, the FDA approved the first tyrosine kinase inhibitor (TKI) for advanced stages of CML, studies have shown that patients taking this oral chemotherapy agent – Gleevac – have a 5-year survival rate of 89% when considering deaths from all causes (IRIS study[1]). Since 2001 new TKIs have been developed that show as good, if not better results, as Gleevac. CML offers just one example of the advances in "targeted cancer therapies."

In the case of Multiple Myeloma, Dr. Zonder is one of, if not the, top prescriber of the drug Lenalidomide in Michigan. This drug is one of the most important advances in treatment of MM in recent years and may also be used in other hematologic cancers. A recent clinical trial, sponsored by the National Cancer Institute[2] has shown that of 568 patients with multiple myeloma, who were randomized to receive

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[1] IRIS: International Randomized study of Interferon and STI571 (GLEEVEC 400 mg QD). IRIS is a randomized, open-label, multicenter, phase III study of 1106 adult patients with newly diagnosed, previously untreated Ph+ CML in CP.

[2] CALGB 100104/ECOG 100104: A Phase III Randomized, Double-Blind Study of Maintenance Therapy With CC-5013 Or Placebo Following Autologous Stem Cell Transplantation For Multiple Myeloma. An overview of the

lenalidomide or placebo, half of the patients receiving the placebo had their myeloma progress (worsen) within slightly over two years. In contrast, for those patients taking lenalidomide, a median time to progression cannot be defined because fewer than half the patients had worsening of their myeloma. This represents a 58 percent reduction in the risk of disease progression for the group taking lenalidomide. This difference in time to progression was highly statistically significant. These results are tremendously significant when you consider that according to the American Cancer Society about 20,520 new cases of multiple myeloma will be diagnosed in 2011 and about 10,610 deaths from multiple myeloma will occur. However treatment with lenalidomide costs approximately $7,000 each month – for a patient with a 20% prescription co-pay, that's $1,400 each month and $16,800 per year.

Most current intravenous cancer chemotherapies lack specificity, killing both cancer and normal cells, and cause unwanted side effects. Oral cancer chemotherapy drugs are designed to target specific cancer-causing molecules, eliminating cancer cells while avoiding serious damage to other, noncancerous cells.

To the benefit of patients, cancer is being treated increasingly with targeted medications and, for an increasing number of cancers, long-term disease control is possible even when a cure is not. Decades of research into cancer cell biology have identified many pathways and mechanisms of cancer cell survival.

Advancements are allowing us to selectively target cancer cells and deliver agents that directly interfere with the cancer cells' survival. These targeted agents generally require continuous exposure to the medication, for which oral therapies are well-suited. Today, oral oncology therapies comprise about 10% available therapies. It is estimated that 25-35% of the medications in the oncology development pipeline are oral therapies. Twenty-four oral agents are currently in Phase III clinical trials, offering hope to patients fighting such cancers as prostate, brain, breast, lung, pancreatic, ovarian, gastric, bone, multiple myeloma, lymphoma and leukemia.

This research and development will result in an increased number of options for patients, but antiquated health insurance benefit designs can create burdens for patients seeking access to the lifesaving medications and for physicians who know that oral therapies are the best option for the patient. As research advances in this field, oral chemotherapies will increasingly become the norm and insurance plans must not allow patient outcomes to be placed in danger due to outdated benefit plans.

Intravenous/infused anti-cancer medications are typically covered under a health plan's medical benefit. In this situation, patients are usually required to pay an office visit co-payment and are not required to pay a separate fee for the drug. Orally-administered anticancer medications, however, are typically covered under a health plan's pharmacy benefit. Under the pharmacy benefit, oral anticancer medications are classified in the highest tier of a health plan's cost-sharing system requiring patients to pay higher co-payments, which can sometimes be a percentage of the drug's cost (e.g. 25-30% of total cost---which can be thousands of dollars each month). This disparity restricts patient access to life-saving oral cancer therapies. When an oral treatment is determined most effective, patients are sometimes forced to make their treatment choice based on cost, rather than efficacy. Whether to incur a large financial burden for an oral chemotherapy can be a life or death decision.

One in three people will be diagnosed with cancer in their lifetime and oral chemotherapies will soon make up close to 50% of the cancer fighting drugs at our disposal - this legislation will one day impact everyone in this room, members of this committee, their friends and family, constituents – and everyone here today testifying in opposition to these bills.

On behalf of the Barbara Ann Karmanos Cancer Institute, our board of directors, physicians, support staff, and most of all our patients, I urge you to support Senate Bills 540 & 541.

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design and entry criteria for this trial can be found at http://www.Cancer.Gov/Clinicaltrials/Calgb-100104 (Clinical Trial Registry number NCT00114101).

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2011 Michigan Public Policy Agenda

- Oral Chemotherapy Coverage
  - KCI supports legislation requiring insurers to provide coverage for oral chemotherapy agents equal to coverage for intravenous chemotherapy agents.
- Healthy Michigan Fund/BCCCP Funding
  - KCI supports appropriations to the Michigan Department of Community Health to maintain and expand the Healthy Michigan Fund and the Breast and Cervical Cancer Control Program.
- Access to Care
  - KCI supports the right of all residents to receive quality care regardless of their healthcare coverage status.
- Addressing Health Disparities
  - KCI believes that disparities in health and wellness among racial and ethnic populations must be addressed through comprehensive statewide cancer control priorities.
- Embryonic Stem Cell Research
  - KCI supports the will of Michigan voters, allowing embryonic stem cell research to be conducted in order to advance scientific progress in the treatment of cancer and other genetic based diseases.
- Smokefree Worksites
  - KCI believes that to reduce cancer incidence in Michigan, residents must remain protected from secondhand smoke in all worksites, including restaurants and bars.
- Certificate of Need Compliance
  - KCI adheres to and maintains compliance with the Certificate of Need process and actively participates in the CoN Commission and all relevant activities.
- Cancer Research Funding
  - KCI supports the establishment of a consistent state budgetary allocation dedicated to cancer research conducted at major research institutes in Michigan.
- Cord Blood Stem Cell Research Network
  - KCI supports the development of a statewide network of FACT accredited cord blood banks to increase the number of units of cord blood available for transplantation and research.
- Medicaid Formulary Preferred Drug List
  - KCI believes that cancer patients receiving Medicaid should have access to all FDA approved treatments and needed medications.

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NCI CCC A Comprehensive Cancer Center Designated by the National Cancer Institute

The Oakland Press (theoaklandpress.com), Serving Oakland County

Opinion

Michigan Needs to Pass the Oral Chemotherapy Access Bills

Monday, November 7, 2011

Imagine you have received a cancer diagnosis and there is a treatment that will manage your disease, limit side effects, allow you to continue working, and can be administered at home. Imagine that you and your physician decide this is the best treatment available - or possibly the only treatment available. Now imagine that this treatment is financially out of reach - simply because it is a pill.

Unfortunately, this scenario is not imaginary; it's very real and occurs every day because many health plans do not cover oral anti-cancer medications at the same level as intravenous or infused anti-cancer medications given in a doctor's office or hospital.

Cancer is treated increasingly with targeted medications and, for an increasing number of cancers, long-term disease control is possible even when a cure is not. Decades of research into cancer cell biology have identified many pathways and mechanisms of cancer cell survival.

The latest anti-cancer drugs are targeted chemicals that inhibit or alter these cellular pathways. Being targeted, the drugs do not have the usual side effects, such as nausea and hair loss. Patients are able to maintain their employment, care for the children and lead a relatively

normal life while fighting their disease.

Unlike traditional (intravenous) chemotherapy, many of these new drugs come only in pill form. As a matter of fact, researchers estimate that between 25% to 35% of promising anti-cancer drugs in development are oral chemotherapy agents. We should be celebrating these new therapies and the future of cancer medicine - new specifically targeted drugs with fewer severe side effects; oral medicines that can be taken at home.

But these new oral anti-cancer drugs are out of reach for many patients even if they have "good" insurance coverage.

Traditional IV chemotherapy is administered at a physician's office or in a hospital infusion clinic. Costs for the IV treatment include not only the anti-cancer drug in the IV bag, but also the administrative costs of an office visit, staffing and medical supplies. Pill chemotherapies, on the other hand, are obtained by patients as "prescription drugs" using a prescription from their oncologist.

Many health insurance plans require patients to pay extremely burdensome out-of-pocket costs for expensive oral anti-cancer medications, while IV anti-cancer medications, which also can be very expensive, are universally covered under patients' hospital care benefits with a negligible co-pay.

Simply put: Insurance plans have not kept up with modern cancer care. Outdated benefit designs make patients responsible for much of the cost of oral anti-cancer drugs, burdening them with thousands of dollars each month. For the majority of patients, in these uncertain economic times, this is simply not possible. The psychological impact on patients

struggling to cover their out-of-pocket costs is devastating.

What can we do about it? Michigan residents can write, email or call their state legislators and ask them to pass the Oral Chemotherapy Access bill (Senate Bills 540 and 541 .) Michigan can join the 14 other states and the District of Columbia in ensuring that patients have access to all anti-cancer medications, regardless of how they are administered, if the Michigan State Legislature passes this bill.

This common-sense legislation, supported by the Barbara Ann Karmanos Cancer Institute, as well as a variety of patient advocacy organizations and health care provider organizations, would not mandate coverage of chemotherapy, but it would require that health plans that cover chemotherapy ensure access to all chemotherapies, regardless of the method of administration.

Ask your health care plan representative if oral chemotherapy is a covered benefit. Don't become a victim of a health insurance plan that does not cover the chemotherapy that could save your life.

The Oral Chemotherapy Access bill is the right thing to do for patients. It's time for Michigan to ensure that cancer patients have access to the medications they need to survive, regardless of how the medication is administered.

Gerold Bepler, M.D., Ph.D., is the President and CEO of the Barbara Ann Karmanos Cancer Institute.
